An ICU Sedation Study

https://www.ed.ac.uk/usher/edinburgh-clinical-trials/our-studies/ukcrc-studies/a2b

@A2BTrial

FAQs – June 2019

NB there was contradictory advice in April and Mays FAQs (well-spotted those who noticed!). The correct version was given in May as below:

Q: What happens if the patient has been discharged from the Trial ICU, but is readmitted within 48 hours of extubation – should they be re-started on the intervention?

A: Yes, you should be collecting data on the patient for 48 hours after extubation anyway, so if they are re-admitted to the Trial ICU and re-intubated, then the intervention should be re-started, just as if they had never left the ICU.

Q: Day 1 Day daily data asks for total sedative drug doses for 24hrs (08:00 to 07:59), same for SOFA score data, blood results and event details. Do we ignore the 08:00 to 07:59 time period for day 1 (which starts at randomisation) and just apply this to all the subsequent days?

A: Yes, for Day 1, please record data for the period from randomisation to 07:59 (unfortunately, at the moment, the generic daily forms in the eCRF are misleading for Day 1)

Q: If a patient is randomised to Propofol (Standard Care), do we have to have to get a delegated Trial prescriber to re-prescribe propofol for the Trial?

A: No, you don't need to have propofol re-prescribed for the Trial (the existing prescription can continue to be used), but it's worth making sure that PRN propofol boluses are prescribed for the management of agitation, particularly for patients randomised to one of the α-2 agonists. This also helps to encourage the nurses to record propofol boluses when given (we collect daily data on all sedatives given).

Q: Do we need to have a prescription to release the trial drugs from pharmacy?

A: No, the Trial drugs can be taken from stock in the ICU, just as if they were being prescribed for non-Trial purposes. All that pharmacy needs to do is make sure that you keep sufficient stock in the ICU, in case patients are randomised to clonidine or dexmedetomidine as part of the Trial.

Q: What happens if a Trial patient requires a procedure such as MRI/CT scan?

A: There is advice on the reverse of the flowcharts about what to do if a study patient requires an operative procedure and this advice holds for transfer for other procedures such as MRI/CT scans too:

- *Increase sedation for transfer to theatre if needed using alpha-2 agonist and/or propofol*
- *Anaesthesia should be administered as per local perioperative guidelines*
- *Continue alpha-2 infusion unless haemodynamically compromised, in which case halve infusion rate and halve again as needed)*

We want to keep the alpha-2 agonist running if possible, not least so that it isn't forgotten about following the procedure and is resumed as the main sedative ASAP afterwards.

Q: Should we be using the same GDPR Information sheet for Prof Legal Representatives, Pers Legal Representatives and Participants?

A: Yes, please use the A2B Data Protection Info sheet V1 27JUL2018 for all of the above

Q: What if our Labs don't report APTT Ratio?

A: Your Lab may report APTT Ratio as APTR (if so, this is what we want), but if they only report APTT, contact them to find out the normal plasma APTT for your lab, then use this as a denominator to use to derive the ratio

I.e. to convert APTT (s) to an APTT Ratio, divide APTT by your lab's normal APTT (round to one decimal place).

You'll need to produce a File Note to document that, on this advice from the Trial Office, you will be deriving the APTT Ratio from the reported APTT in this way, file the original in Section 10 of your ISF and forward The Trial Office a copy for the TMF. Then you should be good to go for the remainder of the Trial!

Q: Does it have to be the Personal Legal Representative who signed the Consent Form that is asked the questions on the Shift Form, or can we ask any visitor?

A: Unfortunately only the individual who acted as the Personal Legal Rep has consented to answer these questions, so you can't ask anyone else. Remember to write the name of the Personal Legal Representative on the Shift Form, so that the bedside nurses know who to ask.

Q: What if a ventilated patient on the trial no longer requires any sedation?

A: If the patient doesn't need any sedation that's fine, but if they do restart it they should receive the randomised drug. Data collection should still continue up to the point the primary endpoint is confirmed (after 48 hours of spontaneous breathing).

Q: For the day of ICU discharge, we have entered the day shift data, but there was no way of recording that the night form wasn't completed because the patient had already been discharged, so we have left the cells blank – is this correct as these are all flagged? There is no facility to enter a comment to explain this in the eCRF.

A: If the shift form hasn't been completed, for whatever reason, you can indicate this in the eCRF, by selecting NO. This will remove queries for the bedside nurse's responses, but if you have to leave blanks for other responses, then you can explain why in response to the queries generated. Provided the discharge is recorded in the ICU discharge tab, we will be able to make sense of the missing data in the analysis.

Q: Re ICE-Q - What if the patient is still not competent at day 30 – does this form get omitted or filled in by proxy (we are aware that the form can be completed up to day 45)?

A: We don't use a proxy for ICE-Q (just for the EQ5D recalled at baseline). If the patient isn't competent to complete ICE-Q and EQ5D between 30-45 days, then they can be omitted. You should just confirm the status check for day 30 and record 30 day follow up as not completed in the Follow-up Tracker tab (dated the end of the window).

Q: Do we need to get a member of the research team who is delegated responsibility to prescribe the IMP on the Delegation Log to rewrite the Trial prescription every time a Kardex is re-written?

A No, the Trial IMP only needs to be prescribed by a delegated member of the research team before when the initial Trial infusion is being started following randomisation. Non-study prescribers can transcribe an existing (current) Trial prescription onto new Kardex, but should include all the information contained in the original prescription.

Q: Does everyone who is on the delegation log as a prescriber have to have protocol (SIV) and GCP training?

A: Yes, everyone who is to prescribe Trial IMP will need to complete protocol and GCP training before they can be added to the delegation log. However, for those who are only going to prescribe IMP or confirm eligibility (doctors), you can use the targeted GCP training slides provided by the Trial Office.

Q: If a patient has been re-intubated, does the re-intubation start a new 48 hour screening window?

A: No, the 48 hour window is from the start of first ventilation in the current ICU admission.

Q: If a patient is “withdrawn from intervention only – follow up and data linkage permitted”, will this mean continuing shift forms?

A: No, you do not need to continue collecting the shift forms or other daily data after the time of withdrawal, but if follow-up is still permitted you should still:

1. *update the patient’s status on the “Change of Status” tab*
2. *Complete the “Final ICU discharge”*
3. *Complete the “Hospital Discharge” tab*
4. *if applicable, complete follow up at 30 days (EQ-5D, recalled EQ-5D & ICE-Q)*